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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,441	03/08/2004	Michael Radomsky	DEPYP003D1C1	1814
22434	7590	06/29/2005	EXAMINER	
BEYER WEAVER & THOMAS LLP P.O. BOX 70250 OAKLAND, CA 94612-0250			HENRY, MICHAEL C	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/796,441

Applicant(s)

RADOMSKY, MICHAEL

Examiner

Michael C. Henry

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The following office action is a responsive to the Amendment filed, 04/18/05.

The amendment filed 04/18/05 affects the application, 10/796,441 as follows:

1. Claims 11 and 17 have amended. Claims 1-10 have been canceled. This leaves claims 11-22. Applicant's timely filed terminal disclaimer has overcome the double patenting rejections of the prior office action.

The responsive to applicants' arguments is contained herein below.

Claims 11-22 are pending in application

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Finkenaar et al. (EP 312208 A1).

In claim 11, applicant claims "A composition for the treatment of diseased, injured or abnormal bone, said composition comprising an effective amount of a growth factor, hyaluronic acid and excipients to maintain biological activity of said factor, said composition being sufficient to enhance bone growth rate and magnitude and having a viscosity and biodegradability sufficient to persist upon application at a site of desired bone growth for a period of time sufficient to enhance said bone growth rate and magnitude." Finkenaar et al. disclose applicant's composition comprising an effective amount of a growth factor (EGF),

Art Unit: 1623

hyaluronic acid having a viscosity of 44,000 cps and water (page 8, example 4, lines 30-49). It should be noted that claim 11 is a composition claim and the intended use of the composition does not add to the patentability of the composition claimed. Furthermore, although Finkenaar et al. is silent about the properties or characteristics of the composition which pertains to its biodegradability and effect of enhancing bone growth rate and magnitude, Mori et al.'s composition is the same as applicant's composition (comprising growth factor, hyaluronic acid of the same viscosity and water as an excipient), and consequently it should inherently possess the same properties. It should be noted that the examiner considers water as being an excipient in the said composition. Claims 13 and 14, which are drawn to compositions of claim 11 wherein the hyaluronic acid is uncrosslinked and hyaluronic acid of specific range of % by weight in solution, are also encompassed by this rejection, since Finkenaar et al. hyaluronic acid is uncrosslinked and contains the same % by weight of hyaluronic acid (i.e., 1%) (page 8, example 4, lines 30-49).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Finkenaar et al. (EP 312208 A1).

Art Unit: 1623

In claim 11, applicant claims "A composition for the treatment of diseased, injured or abnormal bone, said composition comprising an effective amount of a growth factor, hyaluronic acid and excipients to maintain biological activity of said factor, said composition being sufficient to enhance bone growth rate and magnitude and having a viscosity and biodegradability sufficient to persist upon application at a site of desired bone growth for a period of time sufficient to enhance said bone growth rate and magnitude." Claim 12 is drawn to a composition according to claim 11 wherein said viscosity is about 75,000 cp. Dependent claims 15 and 16 are drawn to compositions wherein said growth factor is bFGF, and bFGF of specific concentration (mg/ml) range in the composition.

Finkenaaur et al. disclose a composition comprising an effective amount of a growth factor (EGF), hyaluronic acid having a viscosity of 44,000 cps and water (page 8, example 4, lines 30-49). It should be noted that claim 11 is a composition claim and the intended use of the composition does not add to the patentability of the composition claimed. Also, it should be noted that the examiner considers water as being an excipient in the said composition.

The difference between applicant's claimed composition and the composition taught by Finkenaaur et al. is that the applicant's composition is the viscosity of the composition and the type of FGF used in the composition. However, Finkenaaur et al. disclose that compositions of different viscosities (for example 1,000 to 12,000,000) (see page 2, lines 32-50) and polypeptide growth factors such as basic-FGF (bFGF) can be used (see page 3, lines 36-43).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to prepare a composition comprising a combination of a polypeptide growth

Art Unit: 1623

factor such as bFGF, hyaluronic acid that has a viscosity suggested by Finkenaar et al. and water (as excipient), to treat topical and incisional wounds.

One having ordinary skill in the art would have been motivated to prepare a composition comprising a combination of a polypeptide growth factor such as bFGF, hyaluronic acid that has a viscosity suggested by Finkenaar et al. and water (as excipient), to treat topical and incisional wounds depending on the severity of the wound and the individual that is being treated.

Claims 17-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunstan et al. (WO 95/24211) in view of Brismar (US 5,432,167).

In claim 17, applicant claims "A method of treating diseased, injured or abnormal bone at a site of desired bone growth comprising the step of applying to said site a composition comprising an effective amount of a mixture of hyaluronic acid, a growth factor and excipients to maintain biological activity of said factor, said composition being sufficient to enhance bone growth rate and magnitude and having a viscosity and biodegradability sufficient to persist at said site for a period of time sufficient to enhance said bone growth rate and magnitude."

Dependent claims 18-22 are drawn to a method wherein said viscosity of the composition is about 75,000 cp, the hyaluronic acid is uncrosslinked hyaluronic acid, the hyaluronic acid in said composition is of specific concentration range, the growth factor is bFGF, and bFGF of specific concentration (mg/ml) range in the composition.

Dunstan et al. disclose a method of bone healing with bFGF in BSA in PBS solution (see page 15, lines 2-25 and abstract). In addition, basic FGF (bFGF) is angiogenic "in vivo" (Gospodarowicz et al., (1979) Exp. Eye Res., 28:501-514) and has neurotrophic properties

Art Unit: 1623

(Morrison et al., (1986) Proc. Nat'l Acad. Sci. U.S.A., 83:7537-7541). It should be noted that the examiner considers the BSA in PBS solution, the excipients.

Brismar discloses that hyaluronic acid can be used to treat bone fractures (injured bone) (see abstract and col. 2, lines 47-54).

The difference between applicant's claimed method and the method taught by Dunstan et al. is that the applicant's composition also contains hyaluronic acid and is of a specific viscosity range. However, Brismar discloses that hyaluronic acid can be used to treat bone fractures (injured bone) and the use of compositions containing different amounts of hyaluronic acid, which affect the viscosity of the compositions, depends on factors like the severity of the bone injury or damage and the individual treated.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Dunstan et al. and Brismar, to have used the method of Dunstan et al. to treat injured bone with a composition comprising a combination of a bFGF and hyaluronic acid, since the combination of compounds that are used to treat the same diseases or condition are well known in the art. More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

One having ordinary skill in the art would have been motivated in view of Dunstan et al. and Brismar, to use the method of Dunstan et al. to treat injured bone with a composition comprising a combination of a bFGF and hyaluronic acid, because a skilled artisan would reasonably be expected to prepare a composition comprising a combination of the compounds

Art Unit: 1623

taught by Dunstan et al. and Brismar, to treat bone injury based on type and/or severity of the bone injury.

Response to Arguments

Applicant's arguments with respect to claim 11-22 have been considered but are not found convincing.

The applicant argues that there are no excipients in the composition disclosed by Finkenaar et al. However, Finkenaar et al. disclose water in the composition together with the a growth factor (EGF) and hyaluronic acid (page 8, example 4, lines 30-49). The applicant argues that issue of persistence of the bFGF at the site of desired growth is not addressed since the growth factor is reapplied eleven times over three days. The issue of biodegradability is not addressed since persistence at the site is not an issue. However, Finkenaar et al.'s composition must be sufficient to enhance bone growth rate and magnitude and has a viscosity and biodegradability sufficient to persist upon application at a site of desired bone growth for a period of time since it enhances said bone growth rate and magnitude. The applicant argues that Brismar does not provide a motivation to alter Dunstan, nor does it solve the defects in the teachings of Dunstan. However, both Dunstan and Brismar components are used to treat the same condition (injured bone), thus one would be motivated to combine the two said components to treat the same condition.

The Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1623

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

MCH

June 24, 2005.



**ELVIS Q. PRICE, PH.D.
PRIMARY EXAMINER**